PUBLIC HEALTH COUNCIL

Meeting of the Public Health Council, Tuesday, April 23, 2002, 10:00 a.m., Massachusetts Department of Public Health, 250 Washington Street, Boston, Massachusetts. Public Health Council Members present were: Dr. Howard K. Koh (Chairman), Mr. Manthala George Jr., Ms. Shane Kearney Masaschi (via speaker phone), Ms. Maureen Pompeo and Ms. Janet Slemenda. Ms. Phyllis Cudmore, Mr. Benjamin Rubin and Dr. Thomas Sterne absent (one vacancy). Also in attendance was Attorney Donna Levin, General Counsel.

Chairman Koh announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance, in accordance with the Massachusetts General Laws, Chapter 30A, Section 11A1/2.

The following members of the staff appeared before the Council to discuss and advise on matters pertaining to their particular interests: Ms. Malena Orejuela, Epidemiologist, and Dr. Bruce Cohen,Director, Division of Health Statistics Research and Epidemiology, Bureau of Health Statistics Research and Evaluation; Ms. Karen Granoff, Director and Ms. Stephanie Carter, Managed Care Ombudsman, Office of Patient Protection; Mr. Paul Tierney, Director, Food Protection Program, Division of Food and Drugs; Dr. Paul Dreyer, Director, Division of Health Care Quality; Ms. Joyce James, Director, Ms. Joan Gorga, Program Analyst, Mr. Jere Page, Senior Program Analyst, Determination of Need Program; and Deputy General Counsel, Carl Rosenfield.

RECORDS OF THE PUBLIC HEALTH COUNCIL:

Records of the Public Health Council Meeting of January 22, 2002 and February 26, 2002 were presented to the Council. After consideration, upon motion made and duly seconded, it was voted (unanimously) to approve Records of the Public Health Council Meetings of January 22, 2002 and February 26, 2002.

PERSONNEL ACTIONS:

In a letter dated April 8, 2002, Katherine Domoto, M.D., Associate Executive Director for Medicine, Tewksbury Hospital, Tewksbury, recommended approval of an appointment and reappointments to the medical staff of Tewksbury Hospital. Supporting documentation of the appointees' qualifications accompanied the recommendation. After consideration of the appointees'qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Associate Executive Director for Medicine of Tewksbury Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the following appointment and reappointments to the various medical staffs of Tewksbury Hospital be approved for a period of two years beginning April 1, 2002 to April 1, 2004:

APPOINTMENT:	**STATUS/SPECIALTY:**	**MED. LICENSE NO.:**
Steven Hersch, M.D.	Provisional Consultant/Neurology	210200

REAPPOINTMENTS:	**STATUS/SPECIALTY:**	**MED. LICENSE NO.:**
Natalie Gershman, M.D.	Affiliate Staff/Psychiatry	152859
Paul Heffernan, DPM	Consultant Staff Podiatry	1866
Habib Sioufi, M.D.	Affiliate Staff/Internal Med. Consultant Staff/Pathology	50579
P. Whitney Wolff, M.D.	Active Staff/ Psychiatry	75571
Barbara Wood, DPM	Consultant Staff/Podiatry	1896

In a letter dated April 8, 2002, Mr. Paul Romary, Executive Director, Lemuel Shattuck Hospital, Jamaica Plain, recommended approval of appointments and reappointments to the medical and allied health staffs of Lemuel Shattuck Hospital. Supporting documentation of the appointees' qualifications accompanied the recommendation. After consideration of the appointees' qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Executive Director of Lemuel Shattuck Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the appointments and reappointments to the medical and allied health staffs of Lemuel Shattuck Hospital be approved as follows:

PHYSICIAN INITIAL APPOINTMENT:	**STATUS/SPECIALTY:**	**MED. LICENSE NO:**
Waishun Wong, M.D.	Consultant/Internal Med.	212175

PHYSICIAN RE-APPOINTMENTS	**STATUS/SPECIALTY:**	**MED. LICENSE NO.:**
Douglas Janowski, M.D.	Consultant/Internal Med.	203367
Thomas D. John, DPM	Active/Podiatrist	1853
Amy Lisser, M.D.	Active/Pyschiatry	60303
Anne Pemberton, M.D.	Consultant/Internal Med.	158738
Hedy Smith, M.D.	Consultant/Internal Med.	203148

ALLIED HEALTH PROFESSIONAL INITIAL APPOINTMENT:	**MED. LICENSE NO.:**
Mary Keaveny, RNP	117221

ALLIED HEALTH PROFESSIONAL REAPPOINTMENT:	**MED. LICENSE NO.:**
Myung Woo-Roderick, RNP	181296

STAFF PRESENTATIONS:

"MASSACHUSETTS DEATHS 2000" , BY MALENA OREJUELA, EPIDEMIOLOGIST, BUREAU OF HEALTH STATISTICS, RESEARCH AND EVALUATION:

Ms. Malena Orejuela, Epidemiologist, Bureau of Health Statistics, Research and Evaluation, presented the Massachusetts Deaths 2000 Report to the Council. She said in part, "… Heart disease and cancer remain the leading causes of death in Massachusetts and the Massachusetts death rate for most causes is 6% lower than that for the entire United States….Deaths due to Alzheimer's disease are increasing, making Alzheimer's Disease the sixth leading cause of death in Massachusetts. Among the highlights of Massachusetts Deaths 2000:

1) Overall mortality is relatively stable

- in 2000, a total of 56,591 Massachusetts residents died (1.5% more than in 1999)
- for the third year in a row, the largest number of deaths occurred among persons ages 85 years and over.
-

2) Patterns in leading causes of death remain

- heart disease and cancer remain the leading causes of death (accounting for 52% of all deaths in 2000)
- injury-related deaths continue to be the leading cause of death for persons ages 15-24 years (accounting for over 2/3 of all deaths in that age group)

- Alzheimer's disease is a growing cause of death. In 1999, Alzheimer's Disease debuted as one of the 10 leading causes of death. (Although a code for Alzheimer's previously existed, changes in the assignment of underlying cause of death has led to many more deaths being classified as Alzheimer's Disease. It is now the sixth leading cause of death in Massachusetts).

3) Massachusetts ranks well historically and nationally

- the 2000 Massachusetts age-adjusted death rate was 6% lower than the preliminary 2000 United States rate, and has been consistently lower than the U.S. rate throughout the 1990's

- life expectancy at birth continues to be higher in Massachusetts compared to the U.S. (78.5 years compared to 76.9 years)

- The rate for all firearm deaths in Massachusetts was about one quarter the rate for the United States (2.7 vs. 10.2 deaths per 100,000): 175 persons died from firearm injuries injuries in Massachusetts (a decrease of 3.9% from 1999).

4) HIV/AIDS continues to decline

-There were 226 Massachusetts residents who died from HIV disease in 2000, which represents a continuing downward trend in the number of HIV disease deaths since 1994

-41% of HIV disease deaths were among persons ages 45 years and older. The percentage of HIV disease deaths has been increasing among persons ages 45 years and older since 1995

-There was also a continuing increase in the proportion of female HIV disease deaths, accounting for 29% of all HIV disease deaths.

5) In 2000, suicide rates continue to decline

- There were 401 suicides in 2000, the lowest number in the past decade.

6) In 2000, Massachusetts had the lowest infant mortality rate ever recorded for the state

- The 2000 infant mortality rate ((IMR) was 4.6 deaths per 1,000 live births, 13% lower than in 1999 (5.2 deaths per 1,000 live births)
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- The leading causes of infant death are conditions arising in the perinatal period (61% of all infant deaths), followed by congenital malformations (15% of all infant deaths)
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  In 2000 there were 23 SIDS death compared to 24 deaths in 1999. SIDS was the leading cause of death in post neonatal period, accounting for 7% of all infant deaths.

7) Comparison with Healthy People 2010 Mortality Targets

- Massachusetts either achieved or moved toward most of the Healthy People 2010 Mortality Objectives.

- Massachusetts has achieved 17 targets such as coronary heart disease, firearm

- Massachusetts has achieved 17 targets such as coronary heart disease, firearm
- deaths, motor vehicle –related deaths and homicides
-
- Massachusetts is within 25% of achieving targets for 11 indicators including stroke, prostate cancer, neonatal mortality, and lung cancer
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- Massachusetts is over 25% from achieving targets for 12 indicators such as HIV/AIDS deaths, SIDS deaths, and suicides. Still, these Massachusetts rates are lower than for the United States overall.

8) Disparities in race/ethnicity persist

Disparities in death rates continue; black, non-Hispanic have the highest age-adjusted death rates while Asian/Pacific Islanders have the lowest rates

The death rate for black, non-Hispanics decreased by 0.3% while rates for Hispanics and white, non-Hispanics decreased by 0.3% while rates for Hispanics and white, non-Hispanics increased by 17% and 1%, respectively since 1999. The 17% increase in the death rate for Hispanics is due mainly to the recalculation of the Hispanic population. The Census 2000 count for Hispanics 65 years and older is lower than the number previously estimated. Thus, the death rate (the number of deaths divided by the population) is increased relative to past calculations. The actual number of deaths to persons of Hispanic ethnicity increased only 4% from 1999 to 2000.

STAFF PRESENTATION:

"OFFICE OF PATIENT PROTECTION – A STATUS REPORT ON THE FIRST YEAR OF OPERATION, BY KAREN GRANOFF, DIRECTOR AND STEPHANIE CARTER, MANAGED CARE OMBUDSMAN, OFFICE OF PATIENT PROTECTION:"

Ms. Karen Granoff, Director, Office of Patient Protection, presented a status report on the first year of operation. She said in part, "…The Office was established as a result of legislation that was passed in July of 2000 by former Governor Cellucci. The Department of Public Health is responsible for overseeing part of that law, which includes the external appeal process, overseeing the internal appeal process of the health plans, the continuity of care function, the ombudsman function, the interpretation and posting of data on the Internet, and then there are a few other functions as set forth in Chapter 141. Essentially, when you have a denial from your health plan, you do have the right to file an appeal. The health plan is required by law to resolve that appeal within thirty business days of receipt of the grievance. They have a little more time if medical records are required. They also need to have a process in place for handling expedited appeals. Grievances of adverse determination, which are essentially denials of medical necessity, have to be reviewed in at least one level by a provider who practices in the same or similar specialty as the subject of the appeal. If the subject of the

appeal is in adverse determination, it becomes eligible for external review with the Department of Public Health….Once we receive an appeal here at OPP, the first thing we do is screen it to make sure that it does meet the requirements of the regulations, that the person filing the request is eligible, that it is a service that is covered by the carrier and, if we need additional information, we call the carrier and work with them….The Department of Public Health contracts with three external review agencies. All three are accredited by a national accrediting body and all three provide external review services for many, many other states….There have been issues of communications between behavioral health administrators in the health plans. There have been expedited appeals that were not handled correctly, and in each of these cases we have established corrective action plans for the carriers and the carriers have been very compliant in working through those and in changing the processes that were out of compliance…We were successful in resolving 18 cases in favor of the member through discussions with the carrier, and another three were resolved in favor of the member because the time frames simply were not met. Of the 91 decisions that went out to external review, 76 percent were upheld, 20 percent were overturned, and 4 percent were partially overturned. These statistics are very different than the national average. The national average is about 50/50. So it is showing that the health plans in Massachusetts are doing a pretty good job of making the right decisions the first time around."

"…The number one category of requests in 2001 was for behavioral health issues, and this included people requesting to see a therapist who was not in the health plan's network, or people who were being denied continued inpatient care, when they and their physicians felt it was still medically necessary. The next biggest category was what we call cosmetic surgery, issues where the appellant and the physician is saying the surgery is reconstructive and the health plan is saying no it is not, it is cosmetic. The third biggest category was experimental procedures, procedures that were denied by the health plans because they said it is experimental and, therefore, excluded from coverage, and anything that is denied as experimental always is eligible for external review. The biggest one after that was rehabilitation services, speech therapy, physical therapy and occupational therapy…
In the first three months of 2002, we have received 64 requests for external review, which represents a 236 percent increase from the first quarter of last year. Thirty-nine of those cases were eligible for external review, 18 were not eligible, and 7 were resolved through discussions with the carrier or because they did not meet the time frame. The uphold and overturn rate is largely the same, with 70 percent being upheld, 27 percent being overturned, and at the time that this was put together, there were still 6 cases that we had not yet received decisions on. In terms of the appeal types, behavioral health continues to be the number one category with 29 requests received. Experimental is number two, rehab services is number three, and cosmetic number four. So we are still seeing the same top four categories…The health plans are doing a much better job now of informing people of their rights to request external review, and the numbers really match much more closely what you would expect them to be based on the health plans enrollment. Blue Cross has the largest number of members, so you would expect that they would have more requests, followed by Tufts, Harvard, etc.…"

Ms. Granoff concluded, "Screening the cases offers a lot of opportunities for us to make improvements before the cases go out to external review. We have issued several bulletins jointly with the Division of Insurance, which have helped clarify the regulations for the health

plans and insure greater compliance. We are completing the inspections of the health plans and our next focus is going to be just looking at the behavioral health grievances. We have also been working closely with the Department of Mental Health to look at access to services and to try to see what is going on and where things can be improved. Another thing we are working on is helping to create guidelines for experimental and investigational procedures to try to make things more consistent among the health plans, and this is something that the health plans have agreed to. We are also working to increase the community awareness of the Office of Patient Protection. We are in the process of revising our regulations based on issues and changes that we felt needed to be made as a result of the first year of work, and we are continuing to work collaboratively with the health plans to improve the process, the access to care and the compliance for everybody."

Ms. Stephanie Carter, Managed Care Ombudsman, Office of Patient Protection, said in part, "…The total number of inquiries that we had in 2001 was 2110, and of that, it breaks down to 1585, which we would consider Ombudsman related inquiries. Those would be inquiries about denials of care services or benefits, informational questions about how do I appeal, what do I need to do, questions about what is external review and how do I access that, is it time for me to file for an external review, and questions about OPP and what we do, what services we offer, and information requests about what people's rights are under the law….In terms of the inquiries by plan,…Blue Cross Blue Shield had the most inquiries, then Tufts, Harvard Pilgrim and so on…In terms of the top ten inquiry types, again, very similar to what we saw with external review. The top inquiry type is behavioral health, with similar types of issues: out of network providers, inpatient care not being seen as medically necessary. Pharmacy was also the second highest inquiry type - questions about trying to get a drug covered that is not in the formulary of the plan, being told they do not meet the criteria to get a particular medicine and trying to help them with that. "

PROPOSED REGULATION:

INFORMATIONAL BRIEFING ON 105 CMR 570.000: THE MANUFACTURE, COLLECTION AND BOTTLING OF WATER AND CARBONATED NON-ALCOHOLIC BEVERAGES:

Mr. Paul Tierney, Director, Food Protection Program, Division of Food and Drugs, said in part, "…The reason we are here this morning is to inform the Council that the Division is prepared to move forward to public hearing on the revision of its Regulation 105 CMR 570.000 for the Manufacture, Collection and Bottling of Water and Carbonated Non-Alcoholic Beverages. These regulations have been comprehensively updated to incorporate new federal requirements and to address the concerns of the Massachusetts Senate Committee on Post Audit and Oversight, which issued a report on bottled water two years ago…M.G.L. c. 94, ss 10A through 10G require the licensure of all plants that bottle water or carbonated non-alcoholic beverages for sale in Massachusetts. Currently, local boards of health license in-state plants, and DPH licenses out-of-state plants. In the interest of streamlining enforcement and paperwork, the Department is supporting proposed legislation that would transfer the licensing of all bottling plants to DPH. The bill also specifies that bottles of carbonated non-alcoholic beverages would be regulated as food processors under M.G. L.c. 94, s 305C. Because these

statutory changes are still pending, however, these proposed regulations are based on current law. Given the fact that many food products travel interstate, the Food Protection Program has made a concerted effort over the past several years to adopt federal food standards for the most part when amending DPH's food regulations. Because carbonated non-alcoholic beverages pose little threat to public health and are not included under federal bottled water regulations, they have been exempted from certain requirements of the proposed regulations, such as submission of test results to the Department. The Department proposes to incorporate by reference certain federal regulations: 21 CFR Part 110: Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food; most of 21 CFR Part 129: Processing and Bottling of Bottled Drinking Water; and the standards of identity for bottled water products found in 21 CFR Part 165. Federal manufacturing standards provide a national baseline that all bottlers are required to meet. Federal standards of identity preempt the state from adopting different standards for products that have federal standards."

"…Sources of water for bottled water and carbonated non-alcoholic beverages are approved by DPH, based on a site survey and recommendation from the Massachusetts Department of Environmental Protection (DEP). The proposed regulations specify that this process will occur pursuant to the Memorandum of Understanding between the Departments, finalized in February 2001. The regulations propose that all source water must meet the drinking water requirements established by DEP in 310 CMR 22.00 Source water must be tested at the frequency required by federal law, and, for bottled water sources, test results must be submitted to DPH with the application for a permit and annually thereafter. The proposed regulations require all finished product bottled water and carbonated non-alcoholic beverages to comply with federal standards governing contaminants. Testing must be done at the frequency and in accordance with methods specified by federal law, and test results for bottled water must be submitted to DPH. As in the current regulation, substandard bottled water may not be sold in Massachusetts. Under the proposed regulations, when a harmful substance is suspected or known to be present in a water source or product, or when a source or product is out of compliance with a quality standard, the bottler must notify the Department within 24 hours and must work with the Department to identify and remedy the problem. A product recall section has also been added, based on federal guidelines for product recalls."

Mr. Tierney continued, "Labeling requirements have been updated in the proposed regulations. The federal standards of identity, governing the names of products, have been adopted by reference. Certain new products, such as "iceberg water" and "glacier water," are now being sold by permission of the federal Food and Drug Administration (FDA) … Pursuant to federal requirements that preempt Massachusetts, when the water comes from a public water supply, this must be stated on the label unless the water meets the definition of "purified water" or "sterile water". The draft regulations also contain the requirement, recommended by the Senate Committee, that the permit number be on the label and, for in-state plants, that the city or town issuing the permit be identified. Finally, the proposed regulations require compliance with the general federal food labeling regulations. If DPH receives a complaint of a violation concerning a product that moves in interstate commerce, the regulation states that DPH may refer the complainant to FDA. In addition to the federal manufacturing regulations that are incorporated by reference, the proposed regulations require each plant to have a Sanitation Standard Operating Procedure (SSOP) governing a variety of sanitation issues in the plant.

Also, records of required testing of source water and finished products must be kept for five years. The administration and enforcement sections of the proposed regulations are modeled on 105 CMR 500.000: Good Manufacturing Practices for Food. The Food Protection Program is working towards conforming these provisions in all of DPH's food regulations, while leaving room for appropriate additions or modifications on a product-by-product basis…In preparing this public hearing draft, the Food Protection Program convened an advisory committee composed of both in-state and out-of-state bottlers of water and carbonated non-alcoholic beverages and representatives from local boards of health, DEP, and the Senate Committee on Post Audit and Oversight. The advisory committee provided much useful insight, and the public hearing draft reflects many of its comments. The Food Protection Program intends to hold public hearings on the proposed changes to 105 CMR 570.000 this spring.

NO VOTE, INFORMATIONAL ONLY

FINAL REGULATIONS:

REQUEST APPROVAL OF LICENSURE REGULATIONS FOR ANGIOPLASTY AND CARDIAC SURGERY QUALITY MONITORING AND PATIENT OUTCOME DATA REQUIREMENTS AND RELATED AMENDMENTS TO THE HOSPITAL LICENSURE REGULATIONS:

Dr. Paul Dreyer, Director, Division of Health Care Quality, presented the final regulation to the Council. He said, "I am delighted to bring to the Council for final promulgation and to request the Council's approval of the regulations that require hospitals performing angioplasty and/or cardiac surgery to provide data related to the quality of those services both to the Department and to the appropriate national data registries. The proposed regulations implement the recommendations of the Cardiac Care Quality Commission created by Section 248 of Chapter 159 of the Acts of 2000. In the past, cardiac surgery in Massachusetts has been restricted to academic medical centers. In the year 2000, legislation was enacted committing the Department to the development and operation of new open-heart surgery programs at community hospitals in the Commonwealth. The legislation mandated that the Department require all hospitals in the Commonwealth that perform open-heart surgery to submit patient specific outcome data. The legislation also required the Department, after consulting with the Cardiac Care Quality Advisory Commission, to develop a process for accurately and reliably validating the data. The Department must evaluate all cardiac surgery programs including a case by case analysis of the cardiac procedures at the community hospitals. The Cardiac Care Quality Advisory Commission issued its report in May 2001and recommends that the Department promulgate regulations requiring all cardiac surgery programs and all hospitals performing angioplasty to collect individual patient-level data utilizing the data set of the Society of Thoracic Surgeons (STS) for cardiac surgery data and the National Cardiovascular Data Registry (NCDR) data set for angioplasty data. Other recommendations of the Commission included the development of data analysis center to collect, edit and audit the quality of the data and the requirement that the data be submitted several times per year. The proposed regulations for cardiac surgery and angioplasty require that acute hospitals submit patient-specific cardiac surgery and/or angioplasty data for each

patient receiving cardiac surgery and/or angiography on or after January 1, 2002. The data to be collected incorporate the databases of the STS and the NCDR as well as any supplemental data elements specified by the Department. Hospitals performing cardiac surgery and/or angioplasty after January 1, 2002 are required to be enrolled in or require their physicians to be enrolled in and participate in the database of the STS or, for angioplasty, the NCDR. Hospitals are required to submit patient-specific outcome data in an electronic format quarterly to the Data Analysis Center(DAC), an organization contracted by the Department to receive, process, analyze and report on the cardiac surgery and angioplasty data. Confidentiality of the patient-specific data will be ensured through the required development, implementation and maintenance of administrative procedures by the hospitals. The implementation of the regulations will permit the collection of data needed for the Department to conduct the annual evaluation of all cardiac programs required by the legislation and the determination in March 2004 on whether the implementation of open-heart surgery in community hospitals has resulted in a material benefit to the public and should be expanded to additional programs.

After consideration, upon motion made and duly seconded, it was voted (unanimously) to **approve the Request for Approval of Licensure Regulations for Angioplasty and Cardiac Surgery Quality Monitoring and Patient Outcome Data Requirements and Related Amendments to the Hospital Licensure Regulations**; that a copy of the approved regulations be forwarded to the Secretary of the Commonwealth; and that a copy of the regulations be attached to and made a part of this record as **Exhibit Number 14,735.** The Department conducted a public hearing on April 9 and accepted written testimony through April 16. Testimony at the hearing was presented by Dr. David Torchiana of Massachusetts General Hospital and Dr. Bonnie Weiner of University of Massachusetts Memorial Medical Center. Dr. Weiner was representing the Massachusetts Chapter of the American College of Cardiology.

DETERMINATION OF NEED PROGRAM:

CATEGORY 2 APPLICATIONS:

PROJECT APPLICATION NO. 4-3A13 OF WHITTIER REHABILITATION HOSPITAL TO ADD FIFTEEN (15) REHABILITATION BEDS IN EXISTING AVAILABLE SPACE AT ITS MAIN CAMPUS LOCATED IN WESTBOROUGH, MA:

Ms. Joyce James, Director, Determination of Need Program, addressed the Council. She said, "We are recommending approval in part with conditions of Whittier Rehabilitation Hospital's application to add fifteen (15) rehabilitation beds at its main campus in Westborough. We find that the project meets the requirements set forth by the revised Chronic Disease and Rehabilitation Services for additional beds. The Peter Mantegazza Ten Taxpayer Group submitted comment on the application and requested a public hearing, which was held in January 2002. Contrary to the Ten Taxpayer Group argument, we find no basis to question the reasonableness of the applicant's reported actual and projected occupancy rate and also the capital and operating costs to add those beds. We also find no evidence to support the Ten Taxpayer Group's assertions that the applicant limits access of its rehabilitation services to Medicaid eligible residents residing in the service area."

After consideration, upon motion made and duly seconded, it was voted: (unanimously) to **approve Project Number 4-3A13 of Whittier Rehabilitation Hospital** (a summary is attached to and made a part of this record as **Exhibit Number 14,736)** based on staff findings, with a maximum capital expenditure of $200,000 (October 2001 dollars) and first year incremental operating costs of $560,836 (October 2001 dollars). As approved, the application provides for addition of fifteen (15) acute rehabilitation beds in existing space at the main campus of Whittier Rehabilitation Hospital located at Westborough, MA. This Determination is subject to the following conditions:

1. Whittier shall accept the maximum capital expenditure of $200,000 (October 2001 dollars) as the final cost figure except for those increases allowed pursuant to 105 CMR 100.751 and 752.

2. Whittier shall not transfer any beds (existing or new) either from the facility's main site or existing satellites to other sites for a period of twelve (12) months after adding beds to the hospital's main site under these revised guidelines; provided that a transfer of beds from an existing satellite to a new satellite may be permitted if the transfer does not result in a net increase in satellite beds, the transferred beds are operational at the time the transfer of site application is filed, and the transfer otherwise meets the provisions of 105 CMR 100.720.

PROJECT APPLICATION NO. 3-4893 OF MERRIMACK VALLEY HEALTH SERVICES, INC., TO ACQUIRE A FOURTH MOBILE MAGNETIC RESONANCE IMAGING (MRI) MACHINE TO SERVE FOUR CONSORTIUM MEMBER HOSPITALS:

Ms. Joyce James, Director, Determination of Need Program, addressed the Council. She said, "The Applicant, Merrimack Valley Health Services, Inc., is before you today seeking permission to expand their existing magnetic resonance imaging services through purchase of a fourth full time mobile MRI unit, to provide an additional seven days per week of mobile service. Merrimack Valley Health Services is a non-profit corporation, and comprised of four member hospitals: Anna Jacques Hospital in Newburyport, Lawrence General Hospital in Lawrence, Saints Memorial Medical Center, and Lowell General Hospital, both in Lowell. In addition, Merrimack Valley provides services to Hale Hospital in Haverhill. Staff has reviewed the application using the August 19, 1997 guidelines for magnetic resonance imaging, and the applicant is found to be in compliance with the requirements of the guidelines. Staff recommends approval of the project. The Ten Taxpayer Group filed in conjunction with this application but did not file comments concerning the application..."

After consideration, upon motion made and duly seconded, it was voted, unanimously, to **approve Project Application No. 3-4893 of Merrimack Valley Health Services, Inc.,** (a summary is attached to and made a part of this record as **Exhibit Number 14,737**), based on staff findings, with a maximum capital expenditure of $2,315,000 (November 2001 dollars) and first year incremental operating costs of $913,836 (November 2001 dollars). As approved, the application provides for expansion of MRI service through acquisition of a

fourth unit, a high-field strength mobile Magnetic Resonance Imager (MRI), to serve the existing four consortium member hospitals in Newburyport, Lawrence and Lowell and an additional hospital in Haverhill via a contractual arrangement. This Determination of Need is subject to the following conditions:

1. The applicant shall accept the maximum capital expenditure of $2,315,000 (November 2001 dollars) as the final cost figure except for those increases allowed pursuant to 105 CMR 100.751 and 752.

3. The applicant shall contribute 20% in equity ($463,000 in November 2001 dollars) to the final approved maximum capital expenditure.

4. For Massachusetts residents, the applicant shall not consider ability to pay or insurance status in selecting or scheduling patients for MRI services.

5. The applicant shall appoint a representative from an academic medical center knowledgeable about MRI research activities to the Clinical Oversight Committee before implementation of the project.

6. The applicant shall agree to operate mobile MRI equipment which has pre-market approval by the Food and Drug Administration.

7. The applicant shall provide a total of $115,750 (November 2001 dollars) over five years at $23,150 per year to fund grant-based prevention programs that support the Healthy People 2010 leading indicators. The specific service initiatives and associated funding are described below.

CHNA Community Health Grants: Each Community Health Network Area associated with the member hospitals of the MVHSI including Lowell General Hospital (CHNA #10), Lawrence General Hospital (CHNA #11) and Anna Jacques Hospital (CHNA #12) will award its share of funding through community grants to community based health and wellness organizations based upon recommendations by the Grant Review Committees of each CHNA. All grants will be awarded by a fiscal agent approved by each CHNA. Specific details of the grant award process will be determined through further consultation with the Department and each CHNA. The applicant will file reports, as specified by the Department, detailing the frequency, content and formalities of programming resulting from the grants and evaluations of the programming's effect on the health of service area residents. Such reports shall be filed annually or more frequently if so determined by the DoN Program Director. Funding for this initiative will begin upon project implementation and notification the Department's Office of Healthy Communities.

Note - General Counsel, Ms. Donna Levin, excused herself from discussion of Project Application No. 3-4893, Merrimack Valley Health Services,Inc., citing conflict of interest (268A). Deputy General Counsel Carl Rosenfield acted as Counsel during discussion of this project.

TRANSFER OF OWNERSHIP APPLICATIONS:

PROJECT APPLICATION NO. 4-3A21 OF OLYMPUS OF MASSACHUSETTS, INC. – REQUEST FOR TRANSFER OF OWNERSHIP AND ORIGINAL LICENSURE OF OLYMPUS SPECIALTY HOSPITAL – BRAINTREE, RESULTING FROM ACQUISITION OF THE HOSPITAL'S ASSETS BY MASSACHUSETTS SPECIALTY HOSPITAL, INC. AS PART OF A CHAPTER 11 REORGANIZATION PLAN

PROJECT APPLICATION NO. 4-3A22 OF OLYMPUS OF MASSACHUSETTS, INC. – REQUEST FOR TRANSFER OF OWNERSHIP AND ORIGINAL LICENSURE OF OLYMPUS SPECIALTY HOSPITAL – WALTHAM, RESULTING FROM ACQUISITION OF THE HOSPITAL'S ASSETS BY MASSACHUSETTS SPECIALTY HOSPITAL, INC. AS PART OF A CHAPTER 11 REORGANIZATION PLAN:

Attorney Carl Rosenfield, Deputy General Counsel, Office of the General Counsel, presented the transfer of ownership applications of Olympus of Massachusetts, Inc. He said in part, "Massachusetts Specialty Hospital, Inc., located at 2001 Washington Street, Braintree, MA, is seeking Determination of Need for transfer of ownership and original licensure of Olympus Specialty Hospital- Braintree, a 190-bed chronic/rehabilitation hospital located at 2001 Washington street, MA owned and operated by Olympus of Massachusetts, Inc. This transfer of ownership results from the Applicant's acquisition of the hospital's assets, including those of its satellites at Stoughton and Natick, MA through a purchase and sale agreement with Olympus of Massachusetts, Inc. as part of a Chapter 11 bankruptcy reorganization plan of Olympus Health Group, Inc. and its subsidiaries, including Olympus of Massachusetts, Inc., Goddard Transitional Care Center, LLC, and Perseus of N.E. MA, Inc. Massachusetts Specialty Hospital, Inc. will become the licensee of the hospital following its emergence from bankruptcy..."

"Massachusetts Specialty Hospital, Inc. located at 2001 Washington Street, Braintree, MA is seeking Determination of Need for transfer of ownership and original licensure of Olympus Specialty Hospital-Waltham, located at 775 Trapelo Road, Waltham, MA, owned and operated by Perseus of NE MA, Inc. This transfer of ownership results from the Applicant's acquisition of the hospital's assets through a purchase and sale agreement with Olympus of Massachusetts, Inc. as part of a Chapter 11 bankruptcy reorganization plan of Olympus Health Group, Inc. and its subsidiaries, including Olympus of Massachusetts, Inc., Goddard Transitional Care Center, LLC, and Perseus of N.E. MA, Inc. Massachusetts Specialty Hospital, Inc. will become the licensee of the hospital following its emergence from bankruptcy. No change in services and no capital expenditures are contemplated for this transfer of ownership."

"No change in services and no capital expenditures are contemplated for this transfer of ownership. Based upon a review of the applications submitted and clarification of issues by the Applicant, Staff finds that the applications satisfies the requirements for the Change of Ownership found in 105CMR 100.600 et seq. Staff also finds that the applicant satisfies the standards applied under 100.602 as follows:

A. Individuals residing in the Hospital's primary service areas will comprise a majority of the individuals responsible for decisions concerning:

1. approval of borrowings in excess of $500,000;
2. addition or deletion of a major service;
3. approval of capital and operating budgets; and
4. approval of the filing of an application for determination of need.

B. The Division of Medical Assistance did not submit any comments on access problems for Medicaid recipients in the Hospital's primary service area

C. The Division of Health Care Quality has determined that the Applicant and any health care facility affiliates have not been found to have engaged in a pattern or practice in violation of the provisions of M.G.L. c.111,s.51(D).

D. The Department has determined that the Applicant, a non-acute care hospital, is not subject to a condition of approval to maintain or increase the percentage of gross patient service revenues, as defined at M.G.L. c.6A, s.31, allocated to bad debt and free care for a period of twenty-four (24) months after the proposed transfer has taken place.

E. The Division of Health Care Quality has confirmed that the Applicant is an affiliate of a hospital licensed by the Department.

Regarding item A, only three names with addresses were submitted in the application. As a condition of approval, Staff is recommending that prior to original licensure of the hospital, the Applicant submits to the Director, Determination of Need Program, the names and addresses of individuals residing in the hospital's primary service area who comprise the majority of the local governing board. Residents of the Applicant's service area requested a public hearing on the application. Some residents also submitted comments opposing the application. Both the requests for a public hearing and the comments were withdrawn April 12, 2002."

After consideration, upon motion made and duly seconded, it was voted (unanimously): that **Project Application No. 4-3A21 of Olympus of Massachusetts, Inc. Request for transfer of ownership and original licensure of Olympus Specialty Hospital – Braintree, resulting from acquisition of the hospital's assets by Massachusetts Specialty Hospital, Inc. as part of Chapter 11 reorganization plan be approved**, based on staff findings.

After consideration, upon motion made and duly seconded, it was voted (unanimously): that **Project Application No. 4-3A22 of Olympus of Massachusetts, Inc. – Request for transfer of Ownership and original licensure of Olympus Specialty Hospital – Waltham, resulting from acquisition of the hospital's assets by Massachusetts Specialty Hospital, Inc. as part of a Chapter 11 reorganization plan be approved,** based on staff findings.

COMPLIANCE MEMORANDUM:

PREVIOUSLY APPROVED DON PROJECT NO. 2-3956 OF HEALTH ALLIANCE HOSPITALS – PROGRESS REPORT ON COMPLIANCE WITH CONDITIONS OF APPROVAL FOR TRANSFER OF OWNERSHIP:

Mr. Jere Page, Senior Analyst, Determination of Need Program said in part, "…In the last progress report, we had asked HealthAlliance to provide a written plan for Department approval that had more detail than what had previously been provided and that HealthAlliance has stated its determination to provide a board which is talented and diverse and reflects the communities it services, and it also has agreed to expand the number of organizations it will consult with when board vacancies arise. So, they have provided this new plan. We are confident and they have given us written assurance that they will follow the plan. We are confident that this new, more detailed plan will provide a community review process that effectively identifies and recommends qualified and diverse candidates for the HealthAlliance Board, consistent with our Condition #5."

Mr. Page continued, "Regarding interpreter services, last September there was a vigorous discussion about whether HealthAlliance actually needed a full time Spanish interpreter at the Burbank Campus for five days a week. At HealthAlliance's invitation, the Director of our Office of Multicultural Health, visited the Burbank Campus to provide more assessment on the need for interpreters at Burbank. As a result of her visit, we have come back and recommended modification. The modification says that HealthAlliance will provide sufficient staffing to maintain an interpreter service presence of at least twenty-five hours a week at the Burbank Campus. It is not language specific. It does not require an Hispanic interpreter, just that they maintain that presence…And then mental health, in previous progress reports, there had been some concern about the multiple ambulance transfers between Burbank and Leominster and back to Burbank for the admission to the inpatient rehab unit there. We have been monitoring those numbers of transfers. In the past few months, there has been an average of just one transfer a month. That is not something that we take further action on, or recommend further action. But we do recommend that HealthAlliance continue to monitor that stituation and consider a plan to limit those transfers if the number substantially increases. We have a couple of recommendations to change that interpreter service condition to read that they will provide a presence at the Burbank Campus of at least twenty-five hours a week. We also recommend that they come back in six months for a final progress report in all conditions, one through twelve, and also that, if they are in full compliance with all those conditions, one through twelve, in October, six months from now, then no further progress reports will be required unless they fail to meet, or fail to continue to comply with the conditions."

After consideration, upon motion made and duly seconded, it was voted unanimously to **approve Previously Approved DoN Project No. 2-3956 of HealthAlliance Hospitals – Progress report on compliance with conditions of approval for transfer of ownership**. The modification states that HealthAlliance will provide sufficient staffing to maintain an interpreter service presence of at least twenty-five hours a week at the the Burbank Campus and that they will return in six months for a final progress report in all conditions, one through twelve, and that if they are in full compliance with all conditions, one through twelve in

October, then no further reports will be required unless they fail to continue to comply with the conditions."

The meeting adjourned at 11:20 a.m.

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Howard K. Koh, M.D., M.P.H.
Chairman

LMH/sb